



6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[Docket ID No. EPA-HQ-ORD-2011-0676; FRL-10003-40-ORD]

Availability of the Systematic Review Protocol for the Polychlorinated Biphenyls (PCBs) Noncancer Integrated Risk Information System (IRIS) Assessment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of public comment period.

SUMMARY: The Environmental Protection Agency (EPA) is announcing a 30-day public comment period associated with release of the Systematic Review Protocol for the Polychlorinated Biphenyls (PCBs) Noncancer IRIS Assessment. This document communicates the rationale for conducting the assessment of PCBs, describes screening criteria to identify relevant literature, outlines the approach for evaluating study quality, and describes the process of evidence synthesis/integration and dose-response methods.

DATES: The 30-day public comment period begins **[insert date of publication in the federal register]** and ends **[insert date 30 days after date of publication in the federal register]**.

Comments must be received on or before **[insert date 30 days after date of publication in the federal register]**.

ADDRESSES: The Systematic Review Protocol for PCBs will be available via the Internet on the IRIS website at <https://www.epa.gov/iris>. and in the public docket at <http://www.regulations.gov>, Docket ID: EPA-HQ-ORD-2011-0676.

FOR FURTHER INFORMATION CONTACT: For information on the docket, contact the ORD Docket at the EPA Headquarters Docket Center; telephone: 202-566-1752; facsimile: 202-566-9744; or e-mail: Docket_ORD@epa.gov.

For technical information on the protocol, contact Dr. James Avery, Center for Public Health & Environmental Assessment; telephone: 202-564-1494; or email: avery.james@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Background Information on the IRIS Program and Systematic Review Protocols

EPA's IRIS Program is a human health assessment program that evaluates quantitative and qualitative risk information on effects that may result from exposure to chemicals found in the environment. Through the IRIS Program, EPA provides high quality science-based human health assessments to support the Agency's regulatory activities and decisions to protect public health.

As part of developing a draft IRIS assessment, EPA presents a methods document, referred to as the protocol, for conducting a chemical-specific systematic review of the available scientific literature. EPA is seeking public comment on components of the protocol including the described strategies for literature searches, criteria for study inclusion or exclusion, considerations for evaluating study methods, information management for extracting data,

approaches for synthesis within and across lines of evidence, and methods for derivation of toxicity values. Additionally, key scientific issues that warrant consideration in this assessment are identified in Section 2.5. The protocol serves to inform the subsequent development of the draft assessment and is made available to the public. EPA may update the protocol based on the evaluation of the literature, and any updates will be posted to the docket and on the IRIS website. In accordance with the most current systematic review practices of the IRIS Program, EPA is releasing the PCB protocol to provide similar public engagement steps as other IRIS assessments that have started more recently.

II. How to Submit Technical Comments to the Docket at <http://www.regulations.gov>

Submit your comments, identified by Docket ID No. EPA-HQ-ORD-2011-0676 for PCBs, by one of the following methods:

- <http://www.regulations.gov>: Follow the on-line instructions for submitting comments.
- E-mail: Docket_ORD@epa.gov.
- Fax: 202-566-9744.
- Mail: U.S. Environmental Protection Agency, EPA Docket Center (ORD Docket), Mail Code: 28221T, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. The phone number is 202-566-1752.

- Hand Delivery: The ORD Docket is located in the EPA Headquarters Docket Center, EPA West Building, Room 3334, 1301 Constitution Avenue, N.W., Washington, DC 20229.

The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is 202-566-1744. Deliveries are only accepted during the docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information. If you provide comments by mail or hand delivery, please submit three copies of the comments. For attachments, provide an index, number pages consecutively with the comments, and submit an unbound original and three copies.

Instructions: Direct your comments to EPA-HQ-ORD-2011-0676 for PCBs. Please ensure that your comments are submitted within the specified comment period. Comments received after the closing date will be marked "late," and may only be considered if time permits. It is EPA's policy to include all comments it receives in the public docket without change and to make the comments available online at <https://www.regulations.gov>, including any personal information provided, unless a comment includes information claimed to be Confidential Business Information (CBI) or other information for which disclosure is restricted by statute. Do not submit information through <https://www.regulations.gov> or e-mail that you consider to be CBI or otherwise protected. The <https://www.regulations.gov> website is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide

it in the body of your comment. If you send an e-mail comment directly to EPA without going through <https://www.regulations.gov>, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket, visit the EPA Docket Center homepage at <https://www.epa.gov/dockets>.

Docket: Documents in the docket are listed in the <https://www.regulations.gov> index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other materials, such as copyrighted material, are publicly available only in hard copy. Publicly available docket materials are available either electronically in <https://www.regulations.gov> or as a hard copy at the ORD Docket in the EPA Headquarters Docket Center.

Dated: December 10, 2019.

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Director, Center for Public Health & Environmental
Assessment.

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